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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/799,005 | 03/11/2004 | James Rasmussen | PEPT-P01-005 | 7191 |

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| EXAMINER | |
|---|---|
| SZPERKA, MICHAEL EDWARD | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 10/799,005 | **Applicant(s)** RASMUSSEN ET AL. | |
|---|---|---|---|
| | **Examiner** Michael Szperka | **Art Unit** 1644 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 05 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 1-13.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

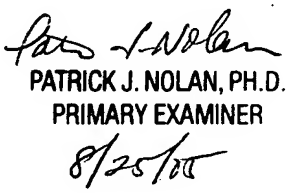
REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments are not persuasive.

Applicant argues that the claimed peptides are different from those taught by Veldman et al. (JI (2004), 172:3883-3892, of record, see entire document). The examiner characterized the peptide epitopes disclosed by Veldman et al. as corresponding to and essentially equivalent to SEQ ID NO:1. As applicant has correctly identified in the response filed August 5, 2005, the DG3(189-205) peptide identified in Table III of Veldman et al. is identical to 16 of the 19 amino acids of SEQ ID NO:1. Claim 1 recites "An isolated polypeptide consisting of an amino acid sequence represented by SEQ ID NO:1". The recitation of the indefinite article "an" opens the scope of the claim to a peptide that is exactly SEQ ID NO:1, as well as fragments of SEQ ID NO:1, said fragments being anything larger than 2 contiguous amino acids located within the full length peptide of SEQ ID NO:1. As such, the data of Veldman that T cells reactive with DG3(189-205) are found in both PV patients and in normal controls is relevant (see particularly Tables I and II). Applicant's further arguments concerning the characterization of the last sentence of the abstract appear incorrect. Based on the data of Table I and II wherein it is shown that both patients and healthy controls have T cells that recognize the same peptides, it is correct to say that the recognition of Dsg3 peptides is independent from the development of PV. Further, the specification does not provide any working examples to indicate that the administration of these peptides is of any therapeutic benefit, and given the teachings of Veldman it is not clear what relevance, if any, this peptide sequence has to PV.

Applicant has also argued that the examiner has failed to consider all the disclosed uses of a peptide of SEQ ID NO:1, indicating on page 4 of the reply filed August 5, 2005 that uses i) and ii) do not recite PV. Use i) is to generate an animal model of autoimmune disease, and ii) is administration of the peptide to induce tolerance. On page 50 of the specification it is clearly indicated that SEQ ID NO:1 is a self epitope implicated in the development of PV. As such, an animal model of autoimmune disease that uses SEQ ID NO:1 would be trying to mimic PV, and not some other autoimmune disease such as multiple sclerosis. As such, the relationship of this epitope to the disease PV is directly relevant. The second use is to induce tolerance. Applicant argues that tolerance can be induced to an epitope even if it has no therapeutic benefit (see particularly the middle of page 4 of the response filed August 5, 2005). If the induction of tolerance has no therapeutic benefit, then this use has no applicable real world utility, and as such is not enabling. In summary, none of applicant's arguments are convincing that the peptide of SEQ ID NO:1 has an enabled use, especially in the absence of evidence to the contrary.



PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
8/25/05